UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,250	11/26/2003	Thomas M. DiMauro	3518.1024-000	6059

21005 7590 05/17/2007

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,250	DIMAURO ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-89* is/are pending in the application.

4a) Of the above claim(s) *11-20,31-59,61-69 and 71-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-10,21-30,60,70 and 89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :17 October 2005, 27 March 2006, 21 September 2006, 17 October 2006, and 14 February 2007.

DETAILED ACTION

Status of the Claims

1. Claims 1-89 are pending in the application, with claims 11-20, 31-59, 61-69, and 71-88 having been withdrawn from consideration, in response to the restriction requirement submitted on March 6, 2007. Accordingly, claims 1-10, 21-30, 60, 70 and 89 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election of the claims of Group I, namely claims 1-10, 21-30, 60, 70 and 89, in the reply filed on March 23, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-20, 31-59, 61-69, and 71-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on March 23, 2007.

The restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on October 17, 2005, March 27, 2006, September 21, 2006, October 17, 2006, and February 14, 2007 is acknowledged.

Specification

3. The use of the trademarks FOSAMAX, DIDRONEL, ACTONEL, REMICADE, HUMIRA, EMBREL, DEPOFOAM, TOLMETIN, SUPROL, TEPOXALIN, and TEFLON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 60 is rejected under 35 U.S.C. 102(b) as being unpatentable over Trieu et al. (US 2002/0026244).

Trieu teaches methods of implanting nucleus pulposus implants (page 1, paragraph [0007]). The method involves removal of the natural nucleus pulposus of the intravertebral disc and implantation of the nucleus pulposus of the invention (page 10, paragraph [0109]). The nucleus pulposus implant of the invention may contain pharmacological agents used to treat

osteoporosis including growth factors, such as fibroblast growth factor and platelet-derived growth factor, and steroids such as estrogen (page 9, paragraphs [0101] and [0104]).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102 (b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-10, 21-30, 70, and 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Radomsky (US 5,942,499) in view of Boyle et al. (US 2003/0207827).

Radomsky teaches a bone growth-promoting composition comprising growth factors such as fibroblast growth factor and platelet-derived growth factor and their methods of use (column 1, lines 19, 35-36, and 61). The invention can be used in various sites of desired bone growth including vertebral compression fractures and in pathological bone defects associated with osteoporosis (column 2, lines 50 and 55-58). The invention describes an injectable mixture of growth factor for intraosseous administration (page 14, column 2, lines 3 and 7).

Radomsky does not teach an anti-resorptive agent and hip bone.

Boyle et al. teach methods to treat bone diseases such as osteoporosis comprising osteoprotegrin, which is a polypeptide that plays a role in promoting bone accumulation (page 1,

paragraphs [0001] and [0006]). Boyle et al. further teach treatment of osteoporosis in postmenopausal women and a direct relationship between osteoporosis and incidence of hip and neck fractures (page 9, paragraph [0095]). Osteoprotegrin acts as a receptor of the TNF family and prevents receptor-ligand interaction (page 4, paragraph [0043]). Osteoprotegrin also blocks interleukin (IL)1-α and IL1-β produced hypercalcemia (page 40, paragraph [0344]). Boyle et al. also teaches that estrogen is a known antiresorptive agent (page 41, paragraph [0355]).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the methods of promoting bone growth comprising a growth factor of Randomsky to be used with an anti-resorptive agent on hip bones because the of Boyle et al. teach the anti-resorptive agent osteoprotegrin as well as treatment of osteoporosis on various bones such as the hip bone and according to Boyle et al., osteoprotegrin can be used to treat osteoporosis in various bones such as the hip.

The motivation to combine the methods of Radomsky to the methods of Boyle et al. is that the methods of Boyle et al. can be used to treat osteoporosis in various bones including the hip bone.

Conclusion

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER